FDA Questions for Panel

QUESTION #1. Totality of Data

Considering the totality of the available information, please discuss the Type III endoleak concern associated with the AFX family of devices, focusing on the currently available AFX product (AFX2):

A. Please discuss the strength of the evidence that the AFX family of devices (and the AFX2 device in particular) is associated with a clinically meaningful increased rate of Type III endoleaks (all Type III endoleaks and Types IIIa and IIIb).

B. Please discuss the effectiveness of the sponsor's mitigation strategies (including device design/manufacturing changes and updated instructions for use) to lower the Type III endoleak risk.

C. Considering your responses to Questions 1A and 1B, please discuss additional strategies (such as such as instructions for use or other labeling changes) that could prevent, mitigate, or treat Type III endoleaks that may be associated with the AFX family of devices, particularly the AFX2 device.

QUESTION #2. Benefit-Risk Profile

Please discuss whether the totality of the data (including postmarket data) continue to support that the benefits of the currently available AFX2 device outweigh the risks.

QUESTION #3. Additional Clinical Data

Please discuss whether additional clinical data are needed to further evaluate the safety and effectiveness of the AFX family of devices, particularly the AFX2 device. If you conclude that additional clinical data are needed, please discuss key study elements such as a registry infrastructure, enrollment criteria, clinical and imaging endpoints, and duration of follow-up.